PATIENT INFORMED CONSENT

THE EFFECTS OF MEMBRANE LIPID REPLACEMENT ON PAIN, FATIGUE AND OTHER SYMPTOMS IN FIBROMYALGIA

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You have the right to know about the procedures and products that are to be used in your participation in a clinical research study so as to afford you an opportunity to make the decision whether or not to join the study after knowing the risks and hazards involved. This disclosure is an effort to make you better informed so that you may give or withhold your consent to participate in this clinical research study. You will have all of the time you need to study this document and decide if you want to take part in the clinical study. This informed consent does not supersede other consent forms that you may have signed. If important, new, relevant information becomes available during the study, you will be made aware of this information in writing.

PURPOSE AND DURATION OF THE STUDY

The purpose of this study is to determine the clinical effectiveness of an all-natural, patented, Food and Drug Administration (FDA)-approved oral lipid nutritional supplement on reducing pain, fatigue and other symptoms and improving quality of life in Fibromyalgia and other related conditions. We will evaluate the efficacy of a dietary product called NTFactor Lipids made by Nutritional Therapeutics, Inc. of New York on pain, fatigue and gastrointestinal symptoms as well as quality of life indicators in adult male and female subjects. The addition of NTFactor Lipids to the diet is expected to improve cellular energy function, decrease fatigue and pain and lower the severity of other symptoms and improve quality of life indicators in Fibromyalgia patients. This study will be a randomized, placebo-controlled, cross-over study. This means that you will be randomly assigned to an initial period in which you will take placebo or dietary supplement. After the initial period, there will be a two-week rest period, and then you will take dietary supplement (or placebo), so that during one part of the trial you will take dietary supplement and the other part placebo.

The study will last 14 weeks. During the first week before the trial a blood sample will be taken (if one has not been taken within the previous two months), and you will be examined by a health care practitioner. If you decide to enter the study, you will be given oral dietary membrane lipid supplement wafers for one-half of the study and placebo wafers for the remainder of the study. You will not be told when you are to receive lipid

supplement or placebo during the study. The dietary lipid supplement to be used in the study is composed completely of non-GMO food and food extracts that will provide a specific fraction of lipids (phospholipids and glycolipids) to repair cellular membrane damage. You will be evaluated by use of a symptom and quality of life scoring system that you will access online using your own computer.

This study is completely voluntary, and you will have the right to withdraw at any time during the study. You will not receive monetary compensation for participation in the trial, but at the end of the trial you will be offered free supplement for participating in the clinical study.

DESCRIPTION OF THE STUDY

Although the causes of Fibromyalgia and similar illnesses are for the most part unknown, the changes associated with pain and fatigue may be due, in part, to loss of cellular energy and sensitivity of nerve networks. In each cell there are energy-generating structures called mitochondria that generate cellular energy and contain their own genetic information that encode some of the proteins of the mitochondria. Mitochondria have their own unique structures that contain membrane lipid molecules that protect the mitochondria and are essential for their function. The polyunsaturated membrane phospholipids (PPC) that are in NTFactor Lipids are essential for mitochondrial structure and function. They are also an important component of cell membranes, including nerve cell membranes, where they function as a barrier molecule and activator of membrane-associated events, such as nerve conduction. They are also important in our gastrointestinal system, providing a barrier and selectively taking in foods that we need for survival. During aging and disease mitochondria are damaged by reactive oxygen metabolites, and this can result in loss of mitochondrial function and changes in mitochondrial genes. PPC are known to protect mitochondria from reactive oxygen metabolites and to repair damaged cellular and mitochondrial membranes. PPCs are the active ingredient of NTFactor, a patented, FDA-approved food additive, along with other natural ingredients.

You will be asked to take an over-the-counter nutritional supplement (NTFactor Lipids®) twice daily to repair damaged cellular membranes and enhance mitochrondrial function. We will determine if this reduces pain and fatigue and other symptoms and improves your quality of life in an approved clinical study. This study will adhere to Good Clinical Practice Guidelines and ethical principals set forth in the Declaration of Helsinki.

This clinical study will utilize the food additive NTFactor Lipids wafers as well as placebo wafers that will taste and feel the same. You may receive the lipid supplement first during the trial, followed by the placebo wafers in the second part of the trial, or you may receive the placebo first during the trial, followed by the supplement wafers in the second part of the trial. This type of clinical trial is called a randomized, double-blind, placebo-controlled, cross-over trial, because all patients will receive the same treatment, but at different times unknown to them or to the Principal Investigators. The test

nutritional supplement to be used has a long record of safety, and over 40 million doses have been taken without negative or adverse events.

At the beginning of the study a sample of blood (approximately one tablespoon) will be removed from a vein in your arm (if this has not been done within the prior 2 months), and you will be given a physical examination, and routine laboratory tests to determine if you have Fibromyalgia or a similar condition and are able to enter the trial. You will also be required to fill out a Combined Symptom Survey Form online on day 0 (before starting), day 1, 2, 3, 7, 14, 21, 28 and 42. At the end of the first 42-day period of the trial you will be asked to return to the clinic, bringing the remainder of the unused supplement/placebo wafers in their bottles with you for counting. After 2 weeks, you will begin to take the next trial supplement (or placebo) wafers, and you will fill out the online Combined Symptom Survey Form on day 0 (before starting the next bottle), day 1, 2, 3, 7, 14, 21, 28 and 42. At the end of the second 42-day period you will return the bottles of supplement/placebo wafers for counting to determine compliance during the trial.

CRITERIA FOR INCLUSION IN THE STUDY

You will be accepted for the study if the following conditions are present:

1. You are an adult male or female, aged 18-64.
2. You have Fibromyalgia or a related clinical condition.
3. You are mobile during the day.
4. You are willing to sign an informed consent document.
5. You are willing to have a teaspoon of blood drawn for analysis.
6. You are willing to take part in a clinical study that will last 14 weeks.
7. You have internet access and an email address.

CRITERIA FOR EXCLUSION FROM THE STUDY

You will not be accepted for the study if the following conditions are present:

1. If you are not an adult.
2. If you do not have Fibromyalgia or a related clinical condition.
3. If you are not mobile, spending more than 10 hours per day in bed.
4. If you are not willing and able to sign an informed consent document.
5. If you are not able to be present at a test location or have a blood draw of 10 cc (4 Tablsp) for blood analysis.
6. If you have unusually high or low values on your blood chemistry screen.
7. If you are pregnant.
8. If you have been declared mentally incompetent by a qualified health care professional.
9. If you have a positive diagnosis of cancer, HIV, hepatitis and other major illnesses, such as severe hypertension, neurodegenerative or autoimmune disease.

10. If you on immune suppressing drugs or medications.
11. If you are legally barred from signing and informed consent document.

EXPECTED RISKS AND DISCOMFORT TO PATIENTS

There are no known side effects or adverse events that may occur because of taking the nutritional supplement in NTFactor Lipids. The supplement can be taken with food or on an empty stomach. Over 40 million doses of NTFactor containing PPC have been consumed with no reported side effects, and there were no side effects reported in previous clinical studies.

No ill-effects are expected from the drawing of 10 cc (4 Tblsp) of blood. You may experience some discomfort as a result of the needle prick in your arm. Although infrequent, the drawing of blood can be associated with some rare side effects, such as local bruising or slight bleeding may occur or other adverse reactions. In extremely rare cases infections at the injection site have occurred. These are usually treated with topical antibiotics. Occasionally, people feel lightheaded or faint when blood is drawn.

If the nutritional supplement is taken and has a beneficial effect on pain, fatigue, gastrointestinal symptoms and quality of life, then it may lessen the effects of Fibromyalgia. No benefits are guaranteed, but previous clinical studies with this supplement suggest that beneficial effects are likely.

Various nutritional supplements have been used to enhance mitochondrial function and decrease mitochondrial changes. The most common among these are anti-oxidants such as vitamin C, CoQ-10 and other dietary supplements. These vitamins and supplements appear to have little effect on Fibromyalgia patients' pain, fatigue and other symptoms. Although oral supplements may cause mild GI upset or irritation, this has not been seen in other clinical studies using this supplement.

I have been assured that confidentiality will be preserved. I understand that representatives from The Institute for Molecular Medicine may inspect the records of this research where appropriate and necessary. My name will not be revealed in any reports or publications resulting from this study, without my expressed consent. It is my understanding that during the course of this study I will be informed of any significant new information that could affect my safety and willingness to continue participation in the study.

I have been given an opportunity to ask any questions concerning the procedure involved, and the investigator has been willing to reply to my inquiries. This procedure will be executed under the above titled and described clinical research protocol at this institution.

I hereby authorize Dr. Paul Breeding_____, the attending physician or investigator and designated associates to perform the procedure.

I have been told and understand that my participation in this clinical research study is

voluntary. I may decide not to participate, or withdraw my consent and discontinue my participation at any time. Such action will be without prejudice, and there shall be no penalty or loss of benefits to which I may otherwise be entitled, and I will continue to receive treatment by my physician.

In addition, I understand that the investigator may discontinue the clinical research study if, in the sole opinion and discretion of investigators, the study or treatment offers me little or no future benefit, or the supply of reagents or materials ceases to be available or other causes prevent continuation of the clinical research study. The investigator will notify me should such circumstances arise, and my physician will advise me about available treatments, which may be of benefit at that time. In addition, my participation could be ended by the sponsoring institution or governmental agencies without regard to my consent.

I will be informed of any new findings developed during the course of this clinical research study, which may relate to my willingness to continue participation.

Should I decide not to participate or withdraw my consent from participation in this clinical research, have been advised that I should discuss the consequences or effects of my decision with my physician.

I will not receive any compensation for my participation in this research study; however, I understand that this is not a waiver or release of my legal rights. At the completion of the study, I will be offered an additional course of the test nutritional supplement.

It is possible that this research project will result in the development of beneficial treatments, new dietary supplements, or possible patentable procedures, in which event I understand that I cannot expect to receive any compensation or benefits from the subsequent use of information acquired and developed through participation in this research project.

I can receive a copy of this form and any other forms that I am required to sign.

I may discuss questions or problems during or after this study with Dr. Paul Breeding at (512) 831-8088 or Dr. Garth L. Nicolson at (949) 715-5978 or Dr. Nancy Russell at (code) number. In addition, I may discuss any problems I may have or any questions regarding my rights during or after this study with the Chairman of the Surveillance Committee at The Institute for Molecular Medicine or the Chairman of the IRB Solutions Committee, and may in the event any problem arises during this clinical research contact the parties named above.

Based upon the above, I consent to undergo the described procedure and have received a copy of the consent form.

SUBJECT AND WITNESS SHALL INITIAL AND DATE ALL PAGES PRECEDING THIS PAGE OF THE CONSENT FORM TO INDICATE THAT THEY HAVE READ

AND UNDERSTAND EACH PAGE.

_____	_____
DATE	SIGNATURE OF PARTICIPANT
_____	_____
WITNESS OTHER THAN PHYSICIAN OR INVESTIGATOR	SIGNATURE OF PERSON RESPONSIBLE

I have discussed this laboratory research study with the participant and/or his or her authorized representative, using a language, which is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks, and I believe the participant understood this explanation.

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PHYSICIAN OR INVESTIGATOR